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Richard S. Ginn

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1645

57360

7590

10/12/2010

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,459	Applicant(s) GINN ET AL.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-10, 14-16 and 20-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-10, 14-16 and 20-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10/10, 9/20/10, 9/23/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on August 10, 2010, September 20, 2010, and September 23, 2010 are being considered by the examiner.

Claim Objections

2. Claim 10 is objected to because of the following informalities: on line 1, "a lumen" should be --the lumen--. Appropriate correction is required.
3. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The limitations of claim 10 are found in the amendment of claim 2 therefore it fails to further limit claim 2.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14, 15, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

After further review of the application, the examiner has noticed that the limitations of claims 14 and 27 are not found in the original disclosure. The original disclosure does not show that the actuator is between the proximal end of the closure element and the outer surface of the elongate member until the distal end of the actuator is coupled with the closure element.

It appears to the examiner that the original disclosure shows that actuator member being coupled to the carrier member and not the closure element.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 14, 15, and 20-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 14 recites the limitation "the proximal end of the closure element" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 20 recites the limitation "the carrier assembly" in line 8. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 29 recites the limitation "the carrier assembly" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2, 3, 5, 7-10, 16, 29-31, 33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (6,110,184) in view of Fontaine et al. (6,447,540)

Weadock discloses the following claimed limitations:

Claims 2 and 10: A method for delivering a closure element (62a-b) to seal an opening through tissue (Fig. 4f), the method comprising: inserting a distal end (40b) of the elongate member into an opening through tissue (Fig. 4a and Col. 8 Lines 64-65), the elongate member having a distal end (40b) and a proximal end (40a), a lumen (43) extending from the distal end to the proximal end (Fig. 2a-b); and a skin (70) overlying at least a portion of the outer surface of the elongate member between the distal end and the proximal end (Fig. 4a) and at least partially overlying a carrier assembly (60) slidably disposed on the elongate member (Fig. 4a-c) and carrying the closure element (Fig. 4a-c and Col. 7 Lines 40-45); deploying one or more medical devices (30, Col. 5 Lines 66-67 to Col. 6 Lines 1-5, and Col. 6 Lines 22-25) through the lumen of the elongated member (Col. 5 Lines 66-67 to Col. 6 Lines 1-5 and Col. 6 Lines 22-25); following removal of the one or more medical devices from within the lumen (Col. 8 Lines 66-67), advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member (Fig. 4a-c), thereby advancing the closure element towards the distal end of the elongate member (Fig. 4a-c); engaging tissue adjacent the distal end of the elongate member with a plurality of tissue engaging elements (outer surface of each ring and 62c-d) on the closure element

(Fig. 4e-f); and withdrawing the elongate member from the opening, thereby leaving the closure element to close the opening (Fig. 4c-e and Col. 9 Lines 46-47).

Claim 8: Wherein the opening through tissue extends through one or more layers of fascia (Fig. 4a where a plurality of layers of fascia have to be passed in order to reach the blood vessel).

Claim 9: Wherein the opening through tissue communicates with a blood vessel, and wherein leaving the closure element to close the opening comprises leaving the closure element to substantially seal the opening from blood flow therethrough with the closure element (Fig. 4a-f and Col. 9 Lines 58-61).

Claim 16: Wherein engaging tissue adjacent the distal end of the elongate member with tissue engaging elements on the closure element comprises deploying the closure element from the carrier assembly and elongate member, the closure element comprising a generally annularly-shaped body comprising proximal and distal ends and a plurality of tissue engaging portions (62c-d) extending from the distal end (Fig. 4d where 62c-d is extending from the distal end of the other rings 62a-b), the closure element being configured to move from a first expanded configuration when on the carrier assembly (Fig. 4a) to a second contracted configuration when deployed (Fig. 4f), thereby drawing tissue around the opening together (Fig. 4f).

Claim 29: Weadock discloses all the limitations of claim 29 (see rejection claims 2, 10, and 16) including that following positioning a guidewire through the opening through tissue inserting a distal end of the elongate member into the opening through tissue along the guidewire (Col. 1 Lines 60-64).

Claim 30: See rejection claim 16

Claim 36: See rejection of claim 9

Weadock discloses the claimed invention, including advancing the carrier assembly towards the distal end, except for a skin, or sleeve member, wherein the carrier assembly causes the skin to separate from the outer surface of the elongate member, the skin comprising a weakened region extending towards the distal end of the elongate member and expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced, and the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Fontaine teaches a skin or sleeve (16) with a weakened region overlying at least a portion of an outer surface between a carrier assembly (20) and a distal end of an elongate member (12) and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member and expand as it advances or moves longitudinally (see abstract and Figure 7). Fontaine also teaches a slippery surface on the sleeve (col. 7, lines 29-38).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Weadock with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (6,110,184) in view of Fontaine et al. (6,447,540) and further in view of Fleischhacker (4,596,559).

Weadock in view of Fontaine disclose the claimed invention, except for the skin comprising a portion of the skin folded over itself to define a flap, the flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin, and wherein the flap is released from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface.

Fleishhacker teaches the skin (combination 12 and 13) comprising a portion of the skin folded over itself to define a flap (22 and 29), the flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin (Fig. 1-5 where the flaps are adjacent to the weakened areas and the proximal end of eth sheath), and wherein the flap is released from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 1-5).

It would have been obvious to one of ordinary skill to provide a skin folded portion to form a flap, as taught by Fleishhacker, to Weadock in view of Fontaine in order to have a locking mechanism that would assure that the skin is not prematurely broken prior to its use.

14. Claims 20-26 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (6,110,184) in view of Fontaine et al. (6,447,540) and further in view of Green et al. (5,674,231).

Weadock discloses the following claimed limitations:

Claim 20: See rejection of claim 2, 16, and 29.

Claim 21: See rejection of claim 16.

Weadock discloses the claimed invention, including advancing the carrier assembly towards the distal end, except for a skin, or sleeve member, wherein the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member, the skin comprising a weakened region extending towards the distal end of the elongate member and expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced, and the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Fontaine teaches a skin or sleeve (16) with a weakened region overlying at least a portion of an outer surface between a carrier assembly (20) and a distal end of an elongate member (12) and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member and expand as it advances or moves longitudinally (see abstract and Figure 7). Fontaine also teaches a slippery surface on the sleeve (col. 7, lines 29-38) and that the skin comprises embedded fibers (82, 66) to bias the skin to preferentially tear (Fig. 14 and 16).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Weadock with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

Weadock in view of Fontaine disclose the claimed invention, except for an obturator with an expandable distal portion.

Green discloses a method for delivering a closure element (22) to seal an opening through tissue (Col. 1 Lines 5-10), the closure element being carried on a carrier assembly (42) inserting a distal end of an obturator (60) disposed within the elongated member through the opening through tissue (Fig. 15). Green further discloses that the obturator comprises an expandable distal portion (combination 62 and 64) coupled with an elongate portion (68) extending proximally for manipulation by a user (Fig. 8-10) and retracting the elongate portion of the obturator in a proximal direction to expand the expandable distal portion distal of the opening through tissue to stabilize or secure tissue surrounding the opening (Fig. 12-15).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Weadock in view of Fontaine with an obturator with an expandable distal end, as taught by Green, in order to maintain the distal end of the elongate member in a desired position with respect to the hole in the wall of the vessel during the hole closing procedure.

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15. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (6,110,184) in view of Fontaine et al. (6,447,540) and further in view of Martinez (5,593,412).

Weadock in view of Fontaine disclose the claimed invention, except for the skin comprising a flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin, and wherein the flap is released from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface.

Martinez teaches the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin (Fig. 1-3 where the flaps are adjacent to the weekend areas (41-45) which attaches all the fingers together as best seen in Fig. 2A) fingers as seen in the figures), and wherein the flap is released from the adjacent region (Fig. 2B-5) as the carrier assembly (14) is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 2-5).

It would have been obvious to one of ordinary skill to provide a skin with flaps, as taught by Martinez, to Weadock in view of Fontaine in order to have a closed tapered area which would facilitate insertion through the tissue prior to separating the skin.

16. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (6,110,184) in view of Fontaine et al. (6,447,540) and further in view of Kanner et al. (5,868,755).

Weadock in view of Fontaine disclose the claimed invention, including the carrier assembly advancing towards the distal end except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface.

Kanner teaches a skin 1 being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface (col. 4, lines 1-16).

It would have been obvious to one of ordinary skill in the art to provide Weadock in view of Fontaine with a skin bonded to the outer surface to the elongate member, as taught by Kanner, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

Response to Arguments

17. Applicant's arguments filed July 28, 2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773